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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/821,203	03/29/2001	Eugenia Wang	WANG 100	5383

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EXAMINER

WHISENANT, ETHAN C

ART UNIT

PAPER NUMBER

1634

DATE MAILED: 10/01/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/821,203

Applicant(s)

WANG, EUGENIA

Examiner

Ethan Whisenant, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply**A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.**

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 21-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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NON-FINAL REJECTION

1. The applicant's Response (filed 03 JUL 03) to the Office Action has been entered. **Claim(s) 21-29** is/are pending. Rejections and/or objections not reiterated from the previous office action are hereby withdrawn. The following rejections and/or objections are either newly applied or reiterated. They constitute the complete set presently being applied to the instant application.

35 USC § 112- 2ND PARAGRAPH

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

CLAIM REJECTIONS under 35 USC § 112- 2ND PARAGRAPH

3. **Claim(s) 21-29** is/are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 21 and the dependent Claims 26-29 is/are indefinite because there is no nexus between the preamble and the claim steps. Claim 21 in its preamble directs to a method which is to accomplish a particular goal. However, none of the claim steps states that this goal is accomplished. For clarity, claimed methods should recite that the purpose of the method has been attained (i.e. provide a nexus between the preamble and the claim steps). Note that the preamble of Claim 21 recites "detecting changes in the expression of genes", however the claim steps never recites that this purpose of the method has been attained. In order to detect changes one must first have a baseline to compare. For example, at time-point X the expression level of gene Y is Z. Then at time-point X+1 following treatment with drug W, the expression level of gene Y is 2Z. Please amend the Claim 21 to make it clear that the claimed method recites that the purpose of the method has been attained (i.e. provide a nexus between the preamble and the claim steps).

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Note that Claim 22 and its dependents Claims 23-25, have not been included in this part of the 112, 2nd paragraph rejection because there is a comparison step in Claim 22 wherein the expression in a first library is compared to that in a second library.

Claim 22 is indefinite because it is unclear what is intended by the phrase "having a different state or expressed to a compound to be tested," on lines 5-6. It is unclear what is meant by the phrase "or expressed to a compound to be tested". Please clarify.

Claim 26 is indefinite because it is unclear what is intended by the phrase "that interacting with genes binding to the E-box regulatory sequence ," on lines 3-4 . Furthermore, Claim 26 is really confusing because the preamble makes it appear that the method is to determine the effect of a compound on a disease or state of an individual, however the method steps don't clearly express how this is to be accomplished. Please review this claim carefully to be sure it saying what you really want it to claim.

REASON FOR ALLOWANCE

4. Claim(s) 21-29 appear to be allowable over the prior art of record because the prior art considered does not teach or reasonably suggest the method for detecting changes in the expression of genes as recited in Claim 21. In particular, the prior art does not teach or reasonably suggest, alone or in combination, providing a set of primers such that the amplicons used to form the array comprise non-consensus sequence such that there is no detectable hybridization with homologous sequences and wherein the all of genes present in the array comprise an E-box regulatory sequence or encode proteins or cofactors that bind to the E-box regulatory sequence.

CONCLUSION

5. Claim(s) 21-29 is/are rejected and/or objected to for the reason(s) set forth above.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ethan Whisenant, Ph.D. whose telephone number is (703) 308-6567. The examiner can normally be reached Monday-Friday from 8:30AM -5:30PM EST or any time via voice mail. If repeated

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attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached at (703) 308-1152.

The fax number for this Examiner is (703) 746-8465. Before faxing any papers please inform the examiner to avoid lost papers. Please note that the faxing of papers must conform with the Notice to Comply published in the Official Gazette, 1096 OG 30 (November 15, 1989). Any inquiry of a general nature or relating to the status of this application should be directed to the group receptionist whose telephone number is (703) 308-0196.

A handwritten signature in black ink, appearing to read 'EWH' or similar, written in a cursive style.

**ETHAN WHISENANT
PRIMARY EXAMINER**